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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/660,862	09/13/00	POLLACK	W ATOPH:52516

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EXAMINER	
FORD, V	
ART UNIT	**PAPER NUMBER**
1645	4

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/660,862	POLLACK, WILLIAM	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1,3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 1 recites the limitation "filtering the thawed concentrated immunoglobulin solution". There is insufficient antecedent basis for this limitation in the claim. It is unclear in the method steps of claim 1 as to which thawed concentrated solution the method is referring to before the filtering step. Do you filter the frozen thawed immunoglobulin solution or the thawed concentrate after the addition of the mono or disaccharide?

3. Claim 3 recites the limitation "adding sodium chloride to the raw immune globulin solution to a final molarity in the range of about 0.03 to 0.05M." It is unclear in the method steps of claim 3 as to what the final molarity is referring to, the molarity of the sodium chloride or the molarity of the raw immunoglobulin or the combination of the two? For examination purposes, the claim will be interpreted to mean the molarity is referring to the molarity of the sodium chloride and clarification as to this point is requested.

4. Claim 3 recites the limitation "lyophilizing the concentrated immunoglobulin solution". There is insufficient antecedent basis for this limitation in the claim. It is unclear in the method steps of claim 3 as to what is lyophilized, the thawed concentrated immunoglobulin solution or the frozen concentrated immunoglobulin solution?

5. Claims 3 and 4 recite the limitation "purified donor plasma pool" There is insufficient antecedent basis for this limitation in the claim. It is unclear in the method steps of claims 3 and 4 as to what the donor plasma pool is purified from? Thus, the metes and bounds of "purified" cannot be ascertained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4 are being rejected under 35 U.S.C. 103(a) as being unpatentable over Zolton et al *(U.S. Patent 4,597,966 published July 1, (1986))* in view of Lundblad *(U.S. Patent published January 29, 1980))* and in further review of Harlow et al *(Antibodies A Laboratory Manual, 1988).*

Claims 1-4 are drawn to a method of manufacturing an immunoglobulin comprising the steps of concentrating a raw immunoglobulin, freezing, thawing and adding a sufficient amount of monosaccharide or disaccharide to the thawed concentrated immunoglobulin solution to yield a solution of about 0.25 to 0.35 osmolar, filtering and lyophilizing. Claim 2 is further drawn to ultrafiltration. Claim 3 is further drawn prior to concentrating a raw immunoglobulin solution, the steps of fractioning the sterilized, purified donor pool to provide a raw immunoglobulin solution and adding sodium chloride to the immunoglobulin solution to a final molarity of about 0.03 to 0.05M. Claim 4 is further drawn to a sterilized, purified donor plasma pool, providing a sterilized donor blood plasma pool, purifying the donor blood plasma pool, adjusting the pH of the purified donor pool to about 6.5 and adjusting the conductivity of the purified donor pool to about 6.5 and adjusting the conductivity to about 3.5 to 6.0 millisiemens.

Zolton et al teaches a method of preparing a stablized highly purified immunoglobulin preparation that comprises a raw immunoglobulin obtained from a sterilized human donor pool which has been frozen individually, thawed, pooled (example 1, column 6, lines 56-68), concentrated by ultrafilitration (example 4, column 7, lines 58-61), L histidine and glycine added to stablize the raw immunoglobulin solution (column 7, lines 64-68 and column 8, line 1-7), filtered and lyophilized (example 6, column 8, lines 13-21), the concentrated raw immunogobulin was washed with 0.023M (i.e. the instant "about 0.03M") sodium chloride buffer prior to ion exchange chromatography (column 7, lines 5-9), pH adjusted to about 6.4 and conductivity adjusted to about 2.7 millisiemens (example 5, column 8 lines 4-7) and the

concentration of the immunoglobulin solution is 5 percent or less more preferably about 0.05 to 5 weight percent and most preferably 1 to about 2 weight percent (column 4, lines 38-41). Zolton et al differs by not teaching that purified antibodies at lower concentrations should be concentrated prior to freezing and also by not teaching the addition of a monosacharide or disaccharide to the raw immunoglobulin.

Harlow et al teaches that purified antibodies at lower concentrations should be concentrated prior to freezing and that any standard method such as ultrafiltration or ammonium sulfate precipitation can be used (paragraph number 2).

Lundblad teaches the use of maltose in immune serum globulin preparations (column 2, lines 24-29) to enhance the solubility of plasma proteins to yield an osmolarity of about 300 mOsm/kg (column 4, lines 50-60, Table II) and provide for increasing the longterm stability of the composition (column 4, line 61-63).

It would be *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to concentrate the raw immunglobulin solution prior to freezing according to one of the methods disclosed by Harlow et al in the preparation method of Zolton et al and to add the maltose in the preparation method of Zolton et al according to Lundblad et al because Lundblad et al teaches that maltose and glycine increase the longterm stability of compositions comprising immunoglobulins.

Status of Claims

7. No claims are allowed.

Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 305-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
April 12, 2001

PATRICIA A. DUFFY
PRIMARY EXAMINER